NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIVUS, INC., Plaintiff, v. ACTAVIS LABORATORIES FL, INC., Defendant.	Civil Action No. 14-cv-3786 (SRC)(CLW) (consolidated with 15-cv-1636 and 15-cv-6256) **OPINION & ORDER**

THIS MATTER comes before the Court on the parties' dispute as to the scope of a discovery confidentiality order ("DCO") in this consolidated patent infringement action. The parties agree that that a DCO should be entered, but were unable to reach an agreement as to some provisions. The Court received letters as well as formal briefing on the issue. In short, Defendant Actavis ("Actavis") proposes a DCO that contains a patent prosecution bar and an FDA regulatory bar or, in the alternative, a two two-tiered structure that precludes the parties' in-house counsel from receiving information designated as highly confidential. Plaintiff Vivus ("Vivus") contends that Actavis cannot demonstrate good cause for such restrictions and maintains that less restrictive DCO provisions are sufficient to safeguard against any potential risk to Actavis. The Court forewent oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure and, for the reasons set forth below, declines to adopt either parties' proposal in full. The Court instead will enter a discovery confidentiality order that strikes a balance between the parties' respective positions and comports with the applicable case law.

I. Background

Vivus brought these patent infringement suits in response to Actavis' filing of an Abbreviated New Drug Application ("ANDA") with the FDA. (Compl., ECF No. 1, ¶ 1; Compl.,

15-cv-1636, ECF No. 1, ¶ 1; Compl., 15-cv-6256, ECF No. 1, ¶ 1.) Actavis seeks approval to commercially market a generic version of Vivus' product, Qsymia (phentermine and topiramate extended release). (Id.) The ten patents ("patents-in-suit") at issue in this consolidated action are owned by Vivus and "cover, *inter alia*, pharmaceutical compositions containing combinations of phentermine and topiramate, and methods of use and administration of combinations of phentermine and topiramate." (Compl., ¶¶ 14-21; Compl., 15-cv-1636, ¶¶ 13-16; Compl., 15-cv-6256, ¶¶ 13-16.) Four patents are entitled "[c]ombination therapy for effecting weight loss and treating obesity[,]" three are entitled "[l]ow dose topiramate/phentermine composition and methods of use thereof[,]" and three are entitled "[e]scalating dosing regimen for effecting weight loss and treating obesity[.]" (Id.) Actavis counterclaims for declaratory relief on the basis of invalidity and non-infringement. (Answer, ECF No. 16; Answer, 15-cv-1636, ECF No. 16; Answer, 15-cv-6256, ECF No. 12.)

Despite the parties' efforts to meet and confer to agree upon a DCO, they "reached an impasse [. . .] with respect to certain levels of confidential access under the DCO." (Letter, ECF No. 56.) The parties then submitted a joint letter detailing their dispute. (Letter, ECF No. 60.) The Court thereafter received supplemental briefing, which includes declarations by an expert for Actavis and by in-house counsel for Vivus, as well as the parties' respective proposals for the disputed DCO provisions. (ECF Nos. 72, 77-78, 83, 88-89, 91.)

II. Legal Framework

A party seeking a protective order must demonstrate good cause for its issuance. Fed.R.Civ.P. 26(c) (providing that a protective order may "requir[e] that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way"); see also In re Deutsche Bank Trust Co. Americas, 605 F.3d 1373, 1378 (Fed.

Cir. 2010) (holding that Federal Circuit law governs such matters in the patent context and applying the Rule 26 good cause standard in assessing a proposed patent prosecution bar). To demonstrate good cause, "the party seeking to limit the disclosure of discovery materials must show that 'specific prejudice or harm will result if no protective order is granted.'" In re Violation of Rule 28(D), 635 F.3d 1352, 1357-58 (Fed. Cir. 2011) (quoting Phillips v. Gen. Motors Corp., 307 F.3d 1206, 1210-11 (9th Cir. 2002)).

While a DCO may provide that sensitive information designated as confidential may be used only for purposes of given case, "there may be circumstances in which even the most rigorous efforts of the recipient of such information to preserve confidentiality in compliance with the provisions of such a protective order may not prevent inadvertent compromise." Deutsche Bank, 605 F.3d at 1378. The Court determines "whether an unacceptable opportunity for inadvertent disclosure exists" on a counsel-by-counsel basis according to the particular facts presented. Id. (quoting U.S. Steel Corp. v. United States, 730 F.2d 1465, 1467-68 (Fed. Cir. 1984)) (internal quotations omitted). In particular, a movant "must show that the information designated to trigger the bar, the scope of activities prohibited by the bar, the duration of the bar, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competitive information." Deutsche Bank, 605 F.3d at 1381.

In addition, the Court retains "broad discretion" to decide what degree of protection is required, and "must balance this risk against the potential harm to the opposing party from restrictions imposed on that party's right to have the benefit of counsel of its choice." Deutsche Bank, 605 F.3d at 1380 (citations omitted). Factors to consider include "the extent and duration of counsel's past history in representing the client before the PTO, the degree of the client's reliance and dependence on that past history, and the potential difficulty the client might face if forced to

rely on other counsel for the pending litigation or engage other counsel to represent it before the PTO." Id. at 1381 (citations omitted).

Importantly, one's general position as in-house counsel is not dispositive of the necessity or scope of a protective order; rather, the Court's inquiry turns on an individual's involvement in "competitive decisionmaking." Deutsche Bank, 605 F.3d at 1378-81 (quoting U.S. Steel, 730 F.2d at 1467-68) (internal quotations omitted). If the moving party establishes the need for a reasonable bar, then the burden shifts to the party seeking an exemption from the bar to demonstrate:

> 1) that counsel's representation of the client in matters before the PTO does not and is not likely to implicate competitive decisionmaking related to the subject matter of the litigation so as to give rise to a risk of inadvertent use of confidential information learned in litigation, and 2) that the potential injury to the moving party from restrictions imposed on its choice of litigation and prosecution counsel outweighs the potential injury to the opposing party caused by such inadvertent use.

Deutsche Bank, 605 F.3d at 1381. An attorney's role may range from insignificant, such as "little more than reporting office actions or filing ancillary paperwork" or "high-altitude oversight of patent prosecution," to "substantial[] engage[ment]" such that "competitive decisionmaking may be a regular part of [her] representation, and the opportunity to control the content of patent applications and the direction and scope of protection sought in those applications may be significant." Id. at 1379-80.

III. Parties' Proposals and Arguments

The provisions at issue appear in paragraphs 9, 15, 19, and 20 of Actavis' proposed DCO. (Proposed DCO, ECF No. 60, Ex. 1, ECF No. 72-4, Ex. 1.) In particular, the instant dispute is encapsulated by the parties' contrasting approaches to paragraph 9, which reflects their divergent views as to the scope of restricted activities and whether such restrictions apply only in the context

of weight-loss patent applications.[1] See Proposed DCO, at 7-10, ¶ 9. Actavis' proposed paragraph 9 provides that any person who receives information or has access to material pursuant to the DCO may not be involved:

> **formally or informally, directly or indirectly,** in the preparation or prosecution of patents involving phentermine and topiramate extended-release products; (ii) **will not be involved in the preparation or prosecution**, of any patents involving phentermine and topiramate extended-release products for a period of one year following the final resolution, including appeals, of this litigation; and (iii) **will not be involved in any petitioning, counseling, or litigation before or involving the FDA** or equivalent foreign agency concerning phentermine and topiramate extended-release products for a period of one year following the final resolution, including appeals, of this litigation.
> [. . .]
> Notwithstanding this or any other provision in the Discovery Confidentiality Order, the Regulatory Bar shall not preclude anyone with access to CONFIDENTIAL or HIGHLY CONFIDENTIAL material from involvement in correspondence or activities before or involving the FDA or equivalent foreign agency relating to obtaining or maintaining approval for a party's own NDA, ANDA, or equivalent foreign application.

(Proposed DCO, at 7-8, ¶ 9 (emphasis added).)

Vivus' proposed paragraph 9 provides that any person who receives information or has access to material pursuant to the DCO may not be involved:

> **in drafting or amending patent claims** in the preparation or prosecution of United States patent applications involving phentermine and topiramate extended-release products **relating to weight loss**; (ii) **will not be involved in drafting or amending patent claims in the preparation or prosecution**, of any United States patent applications involving phentermine and topiramate extended-release products **relating to weight loss** for a period of one year following the final resolution, including appeals, of this litigation; and (iii) **will not be involved in drafting or amending any petition before or involving the FDA** or equivalent foreign agency concerning phentermine and topiramate extended-release products **relating to weight loss** for a period of one year following

[1] Because Actavis seeks comparable relief through its proposed patent prosecution and FDA bars, the Court addresses the propriety of the proposed provisions together unless otherwise noted.

> the final resolution, including appeals, of this litigation. **The patent prosecution bar in this paragraph shall not apply to patent applications directed to methods of use for purposes other than weight loss.**
> [. . .]
> Notwithstanding this or any other provision in the Discovery Confidentiality Order, the Discovery Confidentiality Order shall not preclude anyone with access to CONFIDENTIAL or HIGHLY CONFIDENTIAL material from involvement in: (a) correspondence or activities before or involving the FDA or equivalent foreign agency relating to obtaining or maintaining approval for a party's own NDA, ANDA, or equivalent foreign application; (b) oversight of the preparation or prosecution of patents involving phentermine and topiramate extended-release products; or (c) oversight of petitioning before or involving the FDA or equivalent foreign agency concerning phentermine and topiramate extended-release products.

(Proposed DCO, at 9-10, ¶ 9 (emphasis added).)

In advocating their positions, the parties focus on the role of Vivus' in-house counsel, Dr. Sandra Wells.[2] Dr. Wells serves as "Vice President, Patents and Assistant General Counsel" and certifies that Vivus has "only two in-house attorneys[, . . . and] fewer than 100 employees," with only "two therapies approved by the FDA: Qsymia for chronic weight management and Stendra for erectile dysfunction." (Wells Decl., ECF No. 78-1, ¶¶ 1-3.) Dr. Wells indicates that Qsymia is "the only product that Vivus currently markets and sells itself" and characterizes it as Vivus' "single most important source of revenue." (Id., ¶¶ 3-4.) Of critical importance here, Dr. Wells describes her responsibilities as follows: "overseeing Vivus' outside litigation, patent prosecution, and regulatory counsel[, . . .] oversee[ing] patent prosecution[, . . .] overs[eeing] outside regulatory counsel, which includes oversight of FDA filings and interactions with the FDA[, . . . and]

[2] It bears noting that neither party addresses the "good cause" standard in the context of Vivus' proposed DCO, presumably because Actavis seeks greater restrictions, both parties' proposed restrictions center on the activities of Dr. Wells as opposed to those of Actavis' attorneys and, indeed, Vivus arguably is imposing restrictions on itself through its proposed DCO. In any event, as discussed below, neither party has demonstrated good cause for entry of its preferred DCO and the Court proceeds to enter one that reflects each proposal in part.

[redacted] (Id., ¶¶ 8-10.) Dr. Wells further notes that, "[a]t this time there are pending United States continuation applications relating to weight loss in both families of patents at issue in this case [and] [t]here are also pending United States continuation applications relating to other indications." (Id., ¶ 9.) Dr. Wells represents that she is "the only attorney at Vivus capable of performing all of these duties" and that she is "not involved in competitive decision-making for Vivus." (Id., ¶¶ 11-12.) She further indicates that "John Slebir, the other in-house attorney, is General Counsel and Vice President of Business Development" and "is involved in competitive decision-making." (Id., ¶¶ 1, 11.)

Actavis repeatedly characterizes Vivus' proposal as prohibiting only "pen-to-paper claim drafting" such that there is a "real danger of information misuse" in permitting Dr. Wells to "oversee[] all Qsymia-related prosecution and access[] Actavis' highly sensitive information concerning its similar product" and allowing Dr. Wells to draft petitions for "any phentermine and topiramate extended-release product indicated for any use other than weight loss." (Brief, ECF No. 72, at 2, 15, 19; Reply, ECF No. 83, at 3, 5.) Actavis' expert echoes this sentiment in asserting that, in his experience, "it was essentially unheard of for a company to engage in wholesale disclosure of its confidential technical materials (e.g., current research and development) to V.P. in-house counsel of an adversary." (Butler Decl., ECF No. 72-1, ¶¶ 11-23.) Actavis likewise contends that Vivus' proposal would allow Dr. Wells, equipped with information gleaned from this litigation, to freely supervise outside regulatory counsel who draft FDA Citizen Petitions, i.e., she could, "using the inappropriately acquired confidential information" intentionally or not, file a "Citizen Petition with the FDA against an adversary's product." (Brief, at 2, 16-19; Butler Decl., ¶¶ 20-23.) On this point, Actavis cites a "history of misuse of FDA Citizen Petitions to delay

market entry of generic competitors." (Brief, at 16-17.) Actavis emphasizes [redacted][3] [redacted], as evidence that Dr. Wells would not be able to effectively compartmentalize the knowledge disclosed pursuant to Vivus' proposed DCO. (Letter, ECF No. 88.) Actavis further argues that it "need not put its highly confidential information at risk simply because Vivus has chosen to have a two-member in-house legal team[.]" (Brief, at 13; Butler Decl., ¶¶ 12-13.) Actavis similarly asserts that "Vivus chose to employ only two attorneys out of nearly one hundred employees to support its business, including Qsymia, and only one to manage its litigation, patent prosecution and regulatory activity for Qsymia." (Reply, at 6.) Finally, although "both parties prefer a one-tier DCO, permitting in-house counsel access to litigation materials designated highly confidential," Actavis submits that a two-tiered DCO is appropriate absent adoption of its proffered bars. (Brief, at 3, 19-20.)

By contrast, Vivus argues that "Actavis offers no specific facts in support of its arguments for [its proposed bars], but instead relies on pure speculation." (Opposition, ECF No. 78, at 8.) In addition, Vivus doubts whether Actavis "is seeking indications other than weight loss" and contends that "Actavis also has not articulated any risk to Actavis if Dr. Wells is both allowed access to Actavis' confidential information and continues to prosecute patents concerning phentermine and topiramate that are related to indications other than weight loss." (Id. at 10.) Vivus stresses that "Actavis manufactures an alleged 'risk' based on speculation about a series of possible events in the future," i.e., that Vivus would obtain approval for off-label indications, that

[3] [redacted] (Letter, ECF No. 88.) Actavis alternatively requests that "Dr. Wells not be permitted access under the DCO [redacted] (Id.) For the reasons set forth herein and in light of the DCO to be entered by the Court, this request is denied for want of good cause.

Actavis would seek approval for such indications, and "Vivus would then somehow improperly use information that it obtained about Actavis' ANDA product in this litigation to try to block the potential approval of an Actavis ANDA product for other indications at some unspecified time in the future." (Id. at 15.) Moreover, Vivus maintains that, owing to its size and Dr. Wells' role, Actavis' proposed bars would work substantial prejudice against Vivus. (Id. at 16-17.) Thus, Vivus concludes that Actavis' bars are either too restrictive or redundant and thus altogether unnecessary. (Id.; Letter, ECF No. 60.)

IV. Analysis

First, the Court finds that Actavis has demonstrated that there exists an opportunity for inadvertent disclosure and that reasonable bars are warranted. Indeed, the parties themselves generally agree that some restrictions should be in place (and for an agreed-upon duration), but disagree as to the finer points of such. While the Court declines Actavis' invitation to hold against Vivus its size and personnel decisions and further declines to construe Vivus' proposed bars as literally and exclusively "pen to paper," the risk for inadvertent disclosure nevertheless is increased by both Vivus' limited legal staffing and the duties with which Dr. Wells is entrusted. That is, though Dr. Wells does not explicitly claim to prosecute patents and the Court is wary of generalizations, the record plainly indicates that Dr. Wells performs extensive oversight functions for Vivus with respect to litigation, patent prosecution, and regulatory counsel—again, for a 100-person operation with only two in-house counsel, a centerpiece product, and ten patents at issue here that relate to said product. Compartmentalizing information received in the course of this litigation while continuing to perform one's duties without inadvertent compromise may be difficult under these circumstances. Therefore, the Court accepts that good cause warrants reasonable bars and such bars should more restrictive than those proposed by Vivus so as to

reasonably reflect the risk of disclosure of proprietary competitive information. Vivus' preferences should not predominate such that Actavis' attempts to enter the market are unreasonably imperiled.

The Court next concludes that Vivus has demonstrated that the facts here warrant the imposition of bars less restrictive than those sought by Actavis. First, the Court is no position to discount Dr. Wells' representation that competitive decision-making lies with Vivus' general counsel. Similarly, the Court finds that, in consideration of the particular nature of Vivus' operations as well as the comparative duties of general counsel, Dr. Wells' oversight role is neither insignificant nor substantial engagement. See Deutsche Bank, 605 F.3d at 1379-81. With Dr. Wells thus situated in the middle ground contemplated by Deutsche Bank, the Court is careful to balance the parties' concerns and potential prejudice. See 605 F.3d at 1379-81; Chiesi USA, Inc. v. Sandoz Inc., 41 F. Supp. 3d 417, 424 (D.N.J. 2014) (citing Deutsche Bank, 605 F.3d at 1379-80). Critically, then, although Dr. Wells' role and Vivus' structure support the conclusion that there is a risk of inadvertent disclosure, the Court is not satisfied that Actavis has plausibly articulated harm sufficient to warrant essentially barring Dr. Wells from *any* involvement with phentermine and topiramate for *any* indication during the agreed-upon period. The Court is especially dubious of the likelihood that, as Actavis suggests, Vivus will file a "Citizen Petition with the FDA against [its] product, [intentionally or unintentionally] using the inappropriately acquired confidential information." The patents-in-suit concern weight loss and Actavis only speculates as to how the pursuit of other indications works to Actavis' detriment or is otherwise implicated by the DCO to be entered here. Vivus' proposed weight loss limitation is sufficient to ameliorate the concerns expressed by Actavis. Moreover, Actavis' bars would work considerable prejudice on Vivus by significantly curbing both the duties Dr. Wells would be able to perform as well as Vivus' ability to choose its counsel and pursue its business and litigation strategies. The general possibility of

the unintentional use of confidential information in subsequent FDA- or patent-related proceedings is insufficient to overcome the real prejudice that Actavis' bars impose upon Vivus.

V. Conclusion

Having considered the particular facts presented and having balanced the potential injury to which each party is exposed, the Court concludes that neither party's DCO shall be entered. The Court instead exercises its discretion to enter a DCO that strikes a balance between the parties' competing positions consistent with applicable case law.[4] Such entry shall be without prejudice as the parties may, after properly meeting and conferring, raise issues with respect to access to particular confidential materials or proposed bars on an attorney-by-attorney basis or based on a substantial change in circumstances.

ACCORDINGLY, IT IS on this 21st day of January, 2016,

ORDERED that the parties' respective requests are denied without prejudice and that the Court's discovery confidentiality order shall be entered on the docket;[5] and

ORDERED that this Order shall be placed under seal, with the parties afforded fourteen (14) days to submit, if at all, particularized motions pursuant to Local Rule 5.1 regarding whether the Order shall remain under seal in whole or in part.

s/Cathy L. Waldor
CATHY L. WALDOR
United States Magistrate Judge

[4] Given that the parties initially agreed upon a single-tiered DCO and given that the DCO entered in conformance with this Order addresses the concerns posed by each party, the Court concludes that a two-tiered DCO is unwarranted.
[5] Insofar as the DCO entered by the Court contains language indicating that the entirety of the DCO reflects a joint stipulation, the parties are directed to ignore such language because the DCO entered by the Court is a modification of the document provided by the parties to the Court as a courtesy. As discussed herein, the Court has only modified the paragraphs at issue, i.e., paragraphs 9, 15, 19, and 20.